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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,349	11/16/2001	Victor Gura	30504-2	5267

7590 10/04/2004

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/085,349

Applicant(s)

GURA, VICTOR

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4, 6, 14-16 18-22, 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,269,708 to Bonomimi. Bonomini discloses a wearable dialysis module with capillary fibers that act as dialyzers along with a replaceable filter cartridge 31 that has sorbents that acts to absorb toxins from the dialysis liquid via lines 29 and 23 (see FIG 1, columns 2-5). Bonomini further discloses a blood inlet and outlet (unlabeled, see FIG 1, column 5). Bonomini fails to disclose multiple dialysers or multiple sorbent devices, however, mere duplication of the essential working parts of a device amounts to an obvious duplication of the disclosed prior art. See MPEP 2144.04.

3. Claims 5, 17, 20, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,269,708 to Bonomimi in view of US 4,212,738 to Henne. Bonomini discloses the apparatus as claimed with the exception of a deformable casing to conform to the patient. Henne discloses a wearable dialysis system with a flexible casing that's easily conformed to the body of the patient (see column 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add a flexible casing to the Bonomini portable dialysis system in order to conform to the body of the patient, as taught by Henne. Henne also discloses a multiple-sheet flat membrane dialyzer as

one of the embodiments of his portable dialyzer. The multiple sheets increase the efficiency of the dialyzer (see columns 4, 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a multiple sheet membrane dialyzer in the portable dialysis system disclosed by Bonomini and Henne in order to increase efficiency.

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,269,708 to Bonomimi in view of US 4,212,738 to Henne, further in view of US 4,897,189 to Greenwood. Bonomini and Henne disclose the apparatus as claimed with the exception of a means for injecting anticoagulant into the blood line. Greenwood discloses that his dialysis apparatus includes means for introducing anticoagulants such as heparin into the bloodstream like those well known in the art to prevent patient blood clots (see column 4). These means for injecting may include ports on the blood inlet or outlet. Rearranging parts of an invention requires only routine skill in the art. See MPEP 2144.04 Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add a means for introducing anticoagulants such as heparin into the dialysis system disclosed by Bonomini in order to prevent patient blood clots.

5. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,269,708 to Bonomimi in view of US 3,388,803 to Scott. Bonomini discloses the apparatus as claimed with the exception of a port on the diasylate tube. However, Scott discloses ports 27 and 28 in fluid communication with the diasylate. With regard to applicant's recitation drawn to the manner in which the additives are added, such

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recitation is drawn to the intended use of the device, which does not patentably distinguish from the prior art devices as claimed.

### ***Response to Arguments***

6. Applicant's arguments filed 13 May 2004 have been fully considered but they are not persuasive.

7. In response to applicants argument that the prior art discloses only one sorbent and dialyzer, it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.

8. In response to applicant's argument that the Bonomini device does not perform ultrafiltration and dialysis at the same time, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

9. With regard to applicant's argument that the Bonomini device is not "adapted to enable a patient to wear the whole device", a recitation that an element is "adapted to" perform a function is not a positive limitation, but only requires the ability to so perform. It does not constitute a limitation in any patentable sense.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd   
29 September 2004



ANGELA D. SYKES  
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